VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS

Absender: MIT DER INTERNATIONALEN VORLÄUFIGEN PRÜFUNG BEAUFTRAGTE BEHÖRDE

An:

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PCT

MITTEILUNG ÜBER DIE ÜBERSENDUNG DES INTERNATIONALEN VORLÄUFIGEN PRÜFUNGSBERICHTS
(Regel 71.1 PCT)

Absendedatum *(Tag/Monat/Jahr)*	11.11.2004
Aktenzeichen des Anmelders oder Anwalts: 02/043K NUT	**WICHTIGE MITTEILUNG**

Internationales Aktenzeichen	Internationales Anmeldedatum *(Tag/Monat/Jahr)*	Prioritätsdatum *(Tag/Monat/Jahr)*
PCT/EP 03/07624	15.07.2003	23.07.2002

Anmelder: NUTRINOVA NUTRITION SPECIALITIES & FOOD ...

1. Dem Anmelder wird mitgeteilt, daß ihm die mit der internationalen vorläufigen Prüfung beauftragte Behörde hiermit den zu der internationalen Anmeldung erstellten internationalen vorläufigen Prüfungsbericht, gegebenenfalls mit den dazugehörigen Anlagen, übermittelt.

2. Eine Kopie des Berichts wird - gegebenenfalls mit den dazugehörigen Anlagen - dem Internationalen Büro zur Weiterleitung an alle ausgewählten Ämter übermittelt.

3. Auf Wunsch eines ausgewählten Amts wird das Internationale Büro eine Übersetzung des Berichts (jedoch nicht der Anlagen) ins Englische anfertigen und diesem Amt übermitteln.

4. **ERINNERUNG**

Zum Eintritt in die nationale Phase hat der Anmelder vor jedem ausgewählten Amt innerhalb von 30 Monaten ab dem Prioritätsdatum (oder in manchen Ämtern noch später) bestimmte Handlungen (Einreichung von Übersetzungen und Entrichtung nationaler Gebühren) vorzunehmen (Artikel 39 (1)) (siehe auch die durch das Internationale Büro im Formblatt PCT/IB/301 übermittelte Information).

Ist einem ausgewählten Amt eine Übersetzung der internationalen Anmeldung zu übermitteln, so muß diese Übersetzung auch Übersetzungen aller Anlagen zum internationalen vorläufigen Prüfungsbericht enthalten. Es ist Aufgabe des Anmelders, solche Übersetzungen anzufertigen und den betroffenen ausgewählten Ämtern direkt zuzuleiten.

Weitere Einzelheiten zu den maßgebenden Fristen und Erfordernissen der ausgewählten Ämter sind Band II des PCT-Leitfadens für Anmelder zu entnehmen.

Der Anmelder wird auf Artikel 33(5) hingewiesen, in welchem erklärt wird, daß die Kriterien für Neuheit, erfinderische Tätigkeit und gewerbliche Anwendbarkeit, die im Artikel 33(2) bis (4) beschrieben werden, nur für die internationale vorläufige Prüfung Bedeutung haben, und daß "jeder Vertragsstaat (...) für die Entscheidung über die Patentfähigkeit der beanspruchten Erfindung in diesem Staat zusätzliche oder abweichende Merkmale aufstellen" kann (siehe auch Artikel 27(5)). Solche zusätzlichen Merkmale können z.B. Ausnahmen von der Patentierbarkeit, Erfordernisse für die Offenbarung der Erfindung sowie Klarheit und Stützung der Ansprüche betreffen.

Name und Postanschrift der mit der internationalen Prüfung beauftragten Behörde	Bevollmächtigter Bediensteter
Europäisches Patentamt D-80298 München Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Longo, E Tel. +49 89 2399-8141

PCT/EP2003/007624

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 02/043K NUT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/007624	International filing date (*day/month/year*) 15 July 2003 (15.07.2003)	Priority date (*day/month/year*) 23 July 2002 (23.07.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/575		
Applicant NUTRINOVA NUTRITION SPECIALTIES & FOOD INGREDIENTS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10 February 2004 (10.02.2004)	11 November 2004 (11.11.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/007624

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-16, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-22, filed with the letter of 11 June 2004 (11.06.2004)

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48:3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/ or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 03/07624

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-22	YES
	Claims		NO
Inventive step (IS)	Claims	1-22	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

2. Citations and explanations

This report makes reference to the following documents:

D1: GB 2 329 334

D2: DE 100 63 288.

D4 was not cited in the international search report. A copy of the document is attached.

D4: Pérez-Olleros et al., 1999, Journal of Science of Food and Agriculture, 79, pages 173-178.

1) Novelty

The subject matter of claims 1-22 appears to be novel over the available prior art documents within the meaning of PCT Article 33(2).

2) Inventive step

The subject matter of claims 1-22 appears to involve an inventive step with respect to the available prior art documents within the meaning of PCT Article 33(2).

The problem to be solved by the present application is that of providing a formulation with good cholesterol-reducing properties.

The solution to the problem is an agent which, in addition to cholesterol-reducing active substances such as statines or phytosterines, contains as least one dietary fiber such as carob pulp, a product obtained therefrom, or levan.

D2 is the closest prior art. It describes a mixed drink to which phytosterines are added in order to reduce the cholesterol level of the person who drinks it (see paragraph [0010]). Carob flour can be added as a stabilizer (see claim 13).

D4 describes an antagonistic cholesterol-reducing effect when a combination of carob pulp and carob flour is used, in contrast to the addition of carob pulp only (see page 176, last paragraph).

Therefore, the person skilled in the art was not prompted to combine carob pulp, a product obtained therefrom, or levan with a cholesterol-reducing active substance in order to reduce the cholesterol level synergistically.

3) Industrial applicability
The subject matter of claims 1-22 is industrially applicable within the meaning of PCT Article 33(4).

Patent Claims

1. A cholesterol-reducing agent comprising at least one dietary fiber selected from the group consisting of carob fruit flesh, a product isolated from carob fruit flesh or levan and at least one cholesterol-reducing active ingredient, except for a combination of a) a dietary fiber and b) an aryl-substituted propanolamine derivative or 1,4-benzothiepine 1,1-dioxide derivative.

2. The cholesterol-reducing agent as claimed in claim 1, wherein the dietary fiber or dietary fibers are present in a daily dose of from 1 to 50 g.

3. The agent as claimed in claim 1 or 2, wherein, in addition to carob fruit flesh, a product isolated from carob fruit flesh or levan, one or more dietary fibers from one or more of the following following substances are present: whole grain cereals, oat bran, β-glucan, rice bran, corn bran, barley, Psyllium, guar, carob beans, tragacanth, pectin, inulin, indigestible oligosaccharides, linseed, soy dietary fiber, soy bran, dextrins, arabinoxylans and arabinogalactans.

4. The agent as claimed in claim 1, wherein the dietary fiber is carob fiber.

5. The agent as claimed in claim 1 or 4, wherein the dietary fiber is insoluble in water.

6. The agent as claimed in one of claims 1 to 5, wherein the active ingredient is selected from one or more of the following substances: statins,

inhibitors of bile acid resorption, bile acid sequestrants, fibrates, nicotinic acid derivatives, phytosterols, plant stanols, cholesterol-reducing plant extracts, guglipid and soy protein-containing products.

7. A cholesterol-reducing combination preparation comprising at least one dietary fiber selected from the group consisting of carob fruit flesh, a product isolated from carob fruit flesh or levan and at least one cholesterol-reducing active ingredient, except for an aryl-substituted propanolamine derivative or 1,4-benzothiepine 1,1-dioxide derivative, in separate administration forms.

8. The cholesterol-reducing combination preparation as claimed in claim 7, wherein, in addition to carob fruit flesh, a product isolated from carob fruit flesh or levan one or more dietary fibers from one or more of the following substances are present: whole grain cereals, oat bran, β-glucan, rice bran, corn bran, barley, Psyllium, guar, carob bean seeds, tragacanth, pectin, inulin, indigestible oligosaccharides, carob fruit flesh or a product isolated from carob fruit flesh, linseed, soy dietary fiber, soy bran, dextrins, arabinoxylans and arabinogalactans.

9. The cholesterol-reducing combination preparation as claimed in claim 7 or 8, wherein the dietary fiber or the dietary fibers, in a daily dose of from 1 to 50 g, have at least one cholesterol-reducing active ingredient are present in separate administration forms.

10. The cholesterol-reducing combination preparation as claimed in claim 7, 8 or 9, wherein one or more dietary fibers are foods.

11. The cholesterol-reducing combination preparation as claimed in one of claims 7 to 10, wherein the cholesterol-reducing active ingredient is a food or drug.

12. A method for producing an agent as claimed in one of claims 1 to 6, wherein at least one dietary fiber and at least one cholesterol-reducing active ingredient are mixed with one another.

13. The use of an agent as claimed in one of claims 1 to 6 for producing a drug.

14. The use as claimed in claim 13 for producing a cholesterol-reducing drug.

15. The use as claimed in claim 13 for producing a drug for the prophylaxis of hypercholesterolemia, hyperlipidemia or arteriosclerosis.

16. The use of an agent as claimed in one of claims 1 to 6 for producing a food or a food ingredient.

17. The use as claimed in claim 16 for producing a cholesterol-reducing food or a food ingredient.

18. The use of a combination preparation as claimed in one of claims 7 to 9 for producing a drug.

19. The use as claimed in claim 18 for producing a cholesterol-reducing drug.

20. The use as claimed in claim 18 for producing a drug for the prophylaxis of hypercholesterolemia, hyperlipidemia or arteriosclerosis.

21. The use of an agent as claimed in one of claims 1 to 6 in animal feeding.

22. The use of an agent as claimed in one of claims 1 to 6 for producing a feedstuff.

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